DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

94738d

September 26, 2003

WARNING LETTER
CHI-21-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Phillip D. Horn, President
Horn's Feed Mill, Inc.
205 S. Moore Street
Waterloo, IL 62298

Dear Mr. Horn:

On April 10, 11, and 15, 2003, the Food and Drug Administration (FDA) conducted an inspection at your feed mill located in Waterloo, Illinois. The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000, "Animal Proteins Prohibited in Ruminant Feed" (21 CFR § 589.2000). The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). These deviations cause feed manufactured at your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and misbranded within the meaning of Section 403(f) of the Act. You are also manufacturing a product that is misbranded under section 403(i) of the Act.

Our investigator found the following violations during the inspection:

- Failure to label products that contain or may contain protein derived from mammalian tissues and are intended for use in animal feed with the cautionary statement, "**Do not feed to cattle or other ruminants.**" This is required by 21 CFR § 589.2000(c)(1)(i). The FDA suggests the statement be distinguished by different type size or color, or other means of highlighting the statement so that it is easily noticed by a purchaser. Our inspection found that you are not labeling your Hotline Sow 100 with that caution statement.

- Failure of the label to bear the common or usual name of each ingredient in your [redacted] Sow Concentrate Pellets. Although the January 23, 2003 formula record for your [redacted] Sow Concentrate Pellets indicates that meat was added as

an ingredient, the labeling for this product does not declare animal proteins as an ingredient. As a result, this product is misbranded within the meaning of Section 403(i)(2) of the Act, in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each such ingredient in the food [21 CFR § 101.4(a)(1)].

- Failure to use clean-out procedures or other means adequate to prevent carryover of protein derived from mammalian tissues to animal protein or feeds that may be used for ruminants, to comply with 21 CFR §§ 589.2000(e)(1)(iii)(A) and (B). Specifically, you are not adequately cleaning all common equipment, which is used for the handling of both prohibited protein material and non-prohibited material, as evidenced by:
  - Bulk meat and bone meal is dumped from trucks at the outside pit and then conveyed through the main elevator leg. There is no documentation that the main elevator leg is subsequently flushed with an appropriate material.
  - There is no documentation that the truck used to haul the bulk meat and bone meal is being adequately cleaned.
  - There are no records of visual inspections or physical cleanouts of equipment, including the main [redacted] horizontal mixer. Examination of this mixer by our investigator on April 10, 2003 revealed that a heavy build up of product remained on the mixer shaft, the paddles, and in the bottom of the mixer, after the batch had been dumped.
  - The north bin above the mixer and the pellet cooler/fines system are not included in the routine sequencing/flush procedure.
  - You have not verified that the quantity and type of flush material and/or sequencing strategy is adequate to prevent commingling or cross-contamination of prohibited protein material and non-prohibited material.

In addition, you should be aware that although you maintain some general written clean-out procedures to prevent carryover of protein derived from mammalian tissues to animal protein or feeds that may be used for ruminants, to comply with 21 CFR § 589.2000(e)(1)(iv), the written procedures, even if you were following them, are not sufficient. There are no written procedures that contain detailed cleanout (sequencing, flushing and/or physical cleaning) steps which are specific for your manufacturing facility and operations.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

It is necessary for you to take action on this matter now. Please provide this office a written response within 15 working days of receipt of this letter with the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations and prevent their recurrence. Please include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed.

Your reply should be directed to Patrick J. Brown, Compliance Officer, at the address indicated on the letterhead.

Sincerely,

/S/

Arlyn H. Baumgarten
District Director